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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/919,195
Filing Date: July 31, 2001
Appellant(s): MASSARO ET AL.

Gabor L. Szekeres
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/15/2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 13-28 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Ghaffari, American Journal of Physiology, 276(3, pt. 1), L398-L404, 1999.

Cong, American Journal of Physiology, 275(2, pt. 1), L239-L246, 1998.

Xu, Xiao-Chun, Journal of the National Cancer Institute, vol 89(9), 624-629, 1997.

Wu, The EMBO Journal, vol 16(7), 1656-1669, 1997.

Song, Proc Natl Acad Sci, vol 91, 10809-10813, 1994.

Yu, Respiration Physiology, vol 79, 101-110, 1990.

(10) Grounds of Rejection

Claims 13-28 are rejected under 35 U.S.C. 112, first paragraph and 102(b). This rejection is set forth in a prior Office Action, mailed on 2/17/2004.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 13-28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. As previously stated, the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims do not meet the requirements for adequate written description of the claimed invention because the scope of the claims is unknown due to the structure limitations not being specifically disclosed. There is no description of the identifying characteristics for recognizing that a candidate compound antagonizes RARβ and has specific RAR modulating activity and such antagonist is not specific to at least one other RAR receptor subtype. There are no structural characteristics of such an antagonist provided, nor is there any

indication that applicant had possession of any antagonist. Further, the claimed method required treatment of an unspecified disease. Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claim fails to comply with the written description requirement.

Applicant argues that clarity is not the job of the description requirement but the purpose is to put in the public possession of what the party claims as his own invention. However, if the specification is not clear as to what is the scope of the instant invention, then the invention is not adequately described. The specification does not have adequate written description of what compound do or do not fit within the bounds of the instant claim 13. The only compounds that fit within the bounds of the instant claim 13 are the compounds/methods of the US Patent #6,303,648. The instant specification does not have written description as to how to make compounds that fit within the instant parameters outside the compounds of the parent patent.

3. Claims 13-28 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As stated previously, the claimed invention is drawn to compositions that have RARβ antagonist having specific RAR modulating activity and a method of treating using such compositions. However, the only compounds that are enabled by the instant specification have already been patented. No other

compounds have been suggested or enabled by the instant specification. It is not seen where the instant specification enables the ordinary artisan to make or use the instant invention without undue experimentation.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims: The claims are drawn to any and all known and unknown compounds that have RAR antagonist having specific RAR modulating activity.

3) The state of the prior art: The prior art has specific compounds that have utility as RAR α, β, and γ antagonist activities either specifically or generally to the RAR α, β, and γ. However, the prior art starts with a compound and determines that the compound has certain activity. The prior art does not specify an activity and then searches any and all known and unknown compounds to find one or more that fit the activity.

5) The level of predictability in the art: The level of predictability in the art is low due to the hit or miss style of determining first the compound and then testing the compound

to see if it has the required activity. There is no core of compounds from which to base the predictability from, only an activity that all compounds known and unknown may or may not possess.

6) The amount of direction provided by the inventor: The inventor provides no direction beyond compounds already known (and patented) that have the RAR antagonist activity. There is no guidance as to where to go from the specific compound disclosed on page 16 of the instant specification. The specification provides only a method of testing, not a direction of which to test.

7) The existence of working examples: There is one compound shown on page 16 of the specification. There are no other working examples.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The amount of experimentation needed to make/use the instant invention is unexpected. The test available only gives the test to which a compound can be shown to either have or not have the needed activity. The test does not provide a direction to which the ordinary skilled artisan should proceed other than any and all known and unknown compounds.

Taking the above factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make/use the instant invention without undue experimentation.

The specification does not provide any guidance with exception to the compounds of the parent patent, with respect to any working examples. One skilled in

the art would first have to determine the activity of the receptor in order to develop the claimed invention. If the ordinary artisan doesn't know the structure of what compound meets the particulars of the instant claims, then the ordinary artisan doesn't know how to make the compounds that fulfill the instant claims. Furthermore, no information is presented as to how the undisclosed antagonist compound would have been administered to treat an unspecified disease. Thus, the skilled artisan would not have been able to practice the steps required by the claimed invention.

Applicant argues that the Wands factors are not mandatory and the only relevance is to the facts. The Wands factors illustrate the facts. Due to this, they are relevant to the instant argument. Taking all of the above facts into consideration, it is not seen where the instant specification enables the ordinary artisan to make and use the instant invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 13-28 under 35 U.S.C. 102(b) as being anticipated by Ghaffari, Cong, Xu, Wu, Cao, Song and Yu, is upheld.

As stated previously, Ghaffari discloses compounds that RAR modulation that affects the lung. Cong discloses RAR modulation in its role in the development of the lung. Xu discloses modulation of RAR for lung problems. Wu discloses RAR modulation in lung problems. Cao discloses RAR modulation in the lung tissue. Song discloses RAR modulation in the lung tissue. Yu teaches RAR modulation and its link to the lungs. These all teach RAR modulation and lung tissues. These compounds would inherently encompass the instantly claimed invention.

Applicant argues that the instant claims are not drawn to lung tissue. However, the instant claims (13-20) are drawn to the treatment or prevention of alveolar destruction. The alveolar is in lung tissues. The instant claims (claims 21-28) are drawn to the increase of the gas-exchange surface area of mammalian lungs. This occurs in lung tissues. The cited prior art deals with RAR modulation that affects lung tissues. All of these inherently encompass the instant claims. The prior art teaches a method for treating the same final conditions as is instantly claimed. Due to this, the prior art inherently must have the same activities as instantly claimed. The rejection is upheld.

(11) Response to Argument

1) Applicant's argue that the assertion that the disclosure is insufficient and not enabling to a person of ordinary skill in the art can be enabled by describing the physical or biological properties of a class of compounds which are used in a claimed method.

It is the Examiner's position that the class of compounds to be used in the instantly claimed method is unknown to the ordinary artisan. For a class of compounds to be known by a person of ordinary skill, the class of compounds must be well known within the art. Within the instantly claimed invention, the class of compounds that have capabilities such as being RARβ antagonist having specific RAR modulating activity that is not specific to RARα and RARγ, is not known to the ordinary artisan.

2) Applicant's argue that the law is well established for a new and unobvious use for an old composition is patentable.

It is the Examiner's position that the use of old compositions for a new and unobvious use is patentable. However, the use of an old composition to treat the same disease or condition that was taught by the prior art is not patentable. The only thing novel is the knowledge of the path taken and not the composition nor the end disease/condition treated. The use of aspirin to treat a headache does not become patentable because it is discovered that the physiological path taken to treat the headache with aspirin is by antagonizing a specific receptor.

3) Applicant's argue that the instant specification teaches that the synthesis of candidate compounds having specific RAR modulating activity is well known in the art.

It is the Examiner's position that the instant specification on pages 12-13 teach that RAR ligands having activity are disclosed in other US Patents and the construction of combinatorial libraries of compounds suitable for screening is commonplace. However, the specification does not teach what compounds or class of compounds should be put

into the construction of these combinatorial libraries. These libraries do not currently exist. Applicant has stated that these libraries for screening need to be constructed (page 13 lines 5-6 of the instant specification).

4) Applicant's argue that the term "specific RAR modulating activity" is defined on page 5 lines 17-24.

It is the Examiner's position that the definition of "specific RAR modulating activity" has been defined as having specific receptor activities and has not been defined as a class of compounds. This shows that the class of compounds encompassed by the instant method claims is unknown and can only be discovered by trial and error of testing any and all known and newly discovered compounds.

5) Applicant's argue that determining whether or not a compound has the activity that is encompassed by the instant claims is routine screening.

It is the Examiner's position that the assay needed to determine if a candidate compound has the instantly claimed activity is routine and within the skill of the ordinary artisan. However, the determination of what compound to test is outside the skill of the ordinary artisan. So, to determine if any one compound is covered by the instant method claims, the ordinary artisan would have to test that compound. One compound at a time, in a hit or miss assay without the benefit of a class of compounds to choose from other than the class of all known and future unknown compounds.

6) Applicant's argue that there are numerous structures of broad scope and the numerous specific examples of the patents incorporated by reference the instant specification

teaches a large number of compounds usable in the present invention or suitable for undergoing the routine assays for specific RAR modulating activity and for specific or selective RARβ antagonist activity.

However, it is the Examiner's position that this incorporation by reference of the large scope of compounds only shows that applicant doesn't know what compounds would or would not fit within the scope of the instant claims 13-28 without first testing these compounds. This is a hunting license for activity and not a disclosure of a known and enabled invention. Discoveries of how a receptor relates to a disease/condition is not patentable while the invention of a class of compounds that modulates a receptor to effect a disease/condition is patentable. Applicant has discovered how RAR receptor relates to the condition of alveolar destruction but applicant has not determined what class of compounds fits this activity without first testing any and all known and unknown compounds.

7) Applicant's argue that the claims are broad but the nature of the invention is commensurately broad in that the applicant discovered that antagonists of RARβ retinoid receptors which do not have significant RXR modulating activity, and preferably have no RARα nor RARγ modulating activity, are suitable to be used for curing or preventing certain lung diseases or deficiencies in mammals.

It is the Examiner's position that the claims and the nature of the invention are broad, as applicant admits. The instant claims are not drawn to curing or preventing lung diseases or deficiencies in mammals. The claims are drawn to a method for treatment or

prevention of alveolar destruction. This does not undue any alveolar destruction that has already occurred (cure).

8) Applicant's argue that it is within the skill of the ordinary artisan to screen compounds for activity.

It is the Examiner's position that it is within the skill of the ordinary artisan to screen compounds for activity but it is not within the skill of the ordinary artisan to choose the compounds that should be put through these screening assays when there is no teaching from the specification on how to choose a particular compound to put through these screening assays.

9) Applicant's argue that there are known compounds that modulate retinoid receptors and that these compounds would be likely to be screened for the instant activity.

However, it is the Examiner's position that these compounds being know for having retinoid receptor modulating activity are already known for having the ability to treat alveolar destruction (see the above rejection of the instant claims under 35 USC 102(b) for a sample of these known compounds). These compounds are known for treating alveolar destruction and constitute a patentability bar for the instant claims. This is the reason for the current rejection of the instant claims under 35 USC 102(b) because the instant claims inherently read on the prior art. Compounds having the ability to treat alveolar destruction and having the ability to modulate RAR activity. If these compounds were screened by the ordinary skilled artisans, would be found to have RARβ antagonist activity not specific to RARα or RARγ.

10) Applicant's argue that the instant specification teaches what medical conditions would be treatable by the instant method claims.

However, it is the Examiner's position that while some conditions that can be treated by the instant methods have been disclosed, applicants have not disclosed what are all the conditions that are treatable by the instant method claims.

11) Applicant's argue that anticipatory disclosure must disclose each and every limitation of the anticipated patent claim and the instant rejection of claims under 35 USC 102(b) does not anticipate all the limitations of the instant claims.

However, it is the Examiner's position that the references used in the 35 USC 102(b) rejection meet all the limitations of the instant claims inherently. The prior art used teaches the use of their disclosed compounds to treat alveolar destruction or the increase of gas-exchange surface area by modulating the retinoid receptors. This is the same activity as is claimed by the instant claims. The prior art used does not specifically state what RARα or RARγ do or do not have to do with the activity disclosed in their art. The prior art teaches that the retinoid receptor is modulated and the outcome is the treatment of alveolar destruction and/or the increase of gas-exchange surface area. If the start and the end are the same, then the middle (RARα or RARγ activity) is inherently covered in the absence of a showing to the opposite.

12) Applicant's argue that there is a significant difference between just being a "retinoid" modulator and being selective to RAR receptors and further being selective to RARβ and not RARα nor RARγ.

It is the Examiner's position that this is true. However, if the start (i.e. the main retinoid activity) and the end (i.e. the treatment of alveolar destruction) is the same, then the other aspects (i.e. RARα or RARγ activity) is inherently present in the compounds in the absence of a showing that the RARα or RARγ activity is not the same as instantly claimed.

13) Applicant's argue that there is a need for drugs that have the instantly claimed activity.

It is the Examiner's position that there are currently drugs available that have this activity (see the 102(b) rejection).

14) Applicant's argue that the drugs should be administered as an inhalant.

It is the Examiner's position that the administration of known drugs as an inhalant is known in the art.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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dms
March 16, 2005

Conferees
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